Sanitized DENACOL EX-811/811R

Form Approved. O.M.B. No. 2070-0012. Approval Expires 10-31-96.

U.S. ENVIRONMENTAL PROTECTION AGENCY

AGENCY USE ONLY

Date of receipt

EPA

PREMANUFACTURE NOTICE

Company Sanitized

RECEIVED OPPT CBIC 09 FEB 19 AM 6:03

ICES

in the Premanufacture Notice

Document control number 5109000241 | EPA case number P-09-241

GENERAL INSTRUCTIONS

TS - N A G 0 6 3

- You must provide all information requested in this form to the extent that it is known to or reasonably ascertainable by you. Make reasonable estimates if you do not have actual data.
- Before you complete this form, you should read the "Instructions Manual for Premanufacture Notification" (the Instructions Manual is available from the Toxic Substances Control Act (TSCA) Information Service by calling 202-554-1404, or faxing 202-554-5603).
- If a user fee has been remitted for this notice (40 CFR 700.45), indicate in the boxes above the TS-user fee identification number you have generated. Remember, your user fee ID number must also appear on your corresponding fee remittance, which is sent to EPA, HQ Accounting Operations Branch (PM-226), P.O. 360399M, Pittsburgh, PA 15251-6399, Attn. TSCA User fee.

Part I — GENERAL INFORMATION

You must provide the currently correct Chemical Abstracts (CA) Name of the new chemical substance, even if you claim the identity as confidential. You may authorize another person to submit chemical identity information for you, but your submission will not be complete and the review will not begin until EPA receives this information. A letter in support of your submission should reference your TS user fee identification number. You must submit an original and two copies of this notice including all test data. If you claimed any information as confidential, a single sanitized copy must also be submitted.

Part II — HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

If there are several manufacture, processing, or use operations to be described in Part II, sections A and B of this notice, reproduce the sections as needed.

Part III — LIST OF ATTACHMENTS

Attach additional sheets if there is not enough space to answer a question fully. Label each continuation sheet with the corresponding section heading. In Part III, list these attachments, any test data or other data and any optional information included in the notice.

OPTIONAL INFORMATION

You may include any information that you want EPA to consider in evaluating the new substance. On page 11 of this form, space has been provided for you to described pollution prevention and recycling information you may have regarding the new substance.

So-called "binding" boxes are included throughout this form for you to indicate your willingness to be bound to certain statements you make in this section, such as use, production volume, protective equipment . . . This option is intended to reduce delays that routinely accompany the development of consent orders or Significant New Use Rules. Except in the case of exemption applications (such as TMEA, LVE, LOREX) where certain information provided in such notification is binding on the submitter when the Agency approves the exemption application, checking a binding box in this notice does not by itself prohibit the submitter from later deviating from the information (except chemical identity) reported in the form.

CONFIDENTIALITY CLAIMS

You may claim any information in this notice as confidential. To assert a claim on the form, mark (X) the confidential box next to the information that you claim as confidential. To assert a claim in an attachment, circle or bracket the information you claim as confidential. If you claim information in the notices as confidential, you must also provide a sanitized version of the notice, (including attachments). For additional instructions on claiming information as confidential, read the Instructions Manual.

☒ Mark (x) if any information in this notice is claimed as confidential.

TEST DATA AND OTHER DATA

You are required to submit all test data in your possession or control and to provide a description of all other data known to or reasonably ascertainable by you, if these data are related to the health and environmental effects on the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance. Standard literature citations may be submitted for data in the open scientific literature. Complete test data (written in English), not summaries of data, must be submitted if they do not appear in the open literature. You should clearly identify whether test data is on the substance or on an analog. Also, the chemical composition of the tested material should be characterized. Following are examples of test data and other data. Data should be submitted according to the requirements of §720.50 of the Premanufacture Notification Rule (40 CFR Part 720).

Test Data (Check Below any included in this notice)

- Environmental fate data ☐ Yes
- Health effects data ☒ Yes
- Environmental effects data ☐ Yes
- Physical/Chemical Properties* ☒ Yes
- Other data ☐ Yes
  - Risk assessments
  - Structure/activity relationships
  - Test data not in the possession or control of the submitter

* A physical and chemical properties worksheet is located on the last page of this form.

TYPE OF NOTICE (Check Only One)

☒ PMN (Premanufacture Notice)

☐ INTERMEDIATE PMN (submitted in sequence with final product PMN)

☐ SNUN (Significant New Use Notice)

☐ TMEA (Test Marketing Exemption Application)

☐ LVE (Low Volume Exemption) @ 40 CFR 723.50(c)(1)

☐ LOREX (Low Release/Low Exposure Exemption) @ 40 CFR 723.50(c)(2)

☐ LVE Modification ☐ LOREX Modification

IS THIS A CONSOLIDATED PMN? ☐ Yes

# of chemicals ________
(Prenotice Communication # required, enter # on page 3)

Public reporting burden for this collection of information is estimated to average 110 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M. St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Act (2070-0012), Washington, D.C. 20503.

CERTIFICATION

I certify that to the best of my knowledge and belief:

1. The company named in Part I, section A, subsection 1a of this notice form intends to manufacture or import for a commercial purpose, other than in small quantities solely for research and development, the substance identified in Part I, Section B.

2. All information provided in this notice is complete and truthful as of the date of submission.

3. I am submitting with this notice all test data in my possession or control and a description of all other data known to or reasonably ascertainable by me as required by §720.50 of the Premanufacture Notification Rule.

Additional Certification Statements:

If you are submitting a PMN, Intermediate PMN, Consolidated PMN, or SNUN, check the following **user fee** certification statement that applies:

☒ The Company named in Part I, Section A has remitted the fee of $2500 specified in 40 CFR 700.45(b), or

☐ The Company named in Part I, Section A has remitted the fee of $1000 for an Intermediate PMN (defined @ 40 CFR 700.43) in accordance with 40 CFR 700.45(b), or

☐ The Company named in Part I Section A is a small business concern under 40 CFR 700.43 and has remitted a fee of $100 in accordance with 40 CFR 700.45(b).

If you are submitting a **low volume exemption (LVE)** application in accordance with 40 CFR 723.50(c)(1) or a **Low release and low exposure exemption (LoRex)** application in accordance with 40 CFR 723.50(c)(2), check the following certification statements:

☐ The manufacturer submitting this notice intends to manufacture or import the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of 40 CFR 723.50.

☐ The manufacturer is familiar with the terms of this section and will comply with those terms; and

☐ The new chemical substance for which the notice is submitted meets all applicable exemption conditions.

☐ If this application is for an LVE in accordance with 40 CFR 723.50(c)(1), the manufacturer intends to commence manufacture of the exempted substance for commercial purposes within 1 year of the date of the expiration of the 30 day review period.

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 USC 1001.		**Confidential**
Signature and title of Authorized Official (Original Signature Required) Seiji Nishimura	Date 2/6/2009	
Signature of agent (if applicable)	Date	

Part I -- GENERAL INFORMATION

Section A -- SUBMITTER IDENTIFICATION

Mark () the "Confidential" box next to any subsection you claim as confidential

Confidential

1a. Person Submitting Notice (in U.S.)

Name of authorized official: Seigi Nishimura

Position: President

Company: Nagase America Corporation

Mailing address (number and street): 546 Fifth Avenue, 16th Floor

City, State, ZIP Code: New York, NY 10036-5000

b. Agent (if applicable)

Name of authorized official:

Position:

Company:

Mailing address (number and street):

City, State, ZIP Code:

Telephone: Area Code: Number:

c. If you are submitting this notice as part of a joint submission, mark (X) this box. → ☐

Joint Submitter (if applicable)

Name of authorized official:

Position:

Company:

Mailing address (number and street):

City, State, ZIP Code:

Telephone: Area Code: Number:

2. Technical Contact (in U.S.)

Name of authorized official: Judith Hushon

Position: President

Company: **Chemical Consulting Associates**

Mailing address (number and street): 1659 Chinaberry Ct

City, State, ZIP Code: Naples, FL 34105

Telephone: Area Code: 239 Number: 784-3436

3. If you have had a premotice communication (PC) concerning this notice and EPA assigned a PC Number to the notice, enter the number. →		Mark (X) if none →	☒
4. If you previously submitted an exemption application for the chemical substance covered by this notice, enter the exemption number assigned by EPA. If you previously submitted a PMN for this substance enter the PMN number assigned by EPA (i.e. withdrawn or incomplete). →		Mark (X) if none →	☒
5. If you have submitted a notice of Bona fide intent to manufacture or import for the chemical substance covered by this notice, enter the notice number assigned by EPA. →		Mark (X) if none →	☒

6. Type of Notice - Mark (X)	1. ☐	Manufacture Only	2. ☒	Import Only	3. ☐ Both
	☐	Binding Option	☒	Binding Option Mark (X)	

Part I -- GENERAL INFORMATION -- Continued

Section B -- CHEMICAL IDENTITY INFORMATION: You must provide a currently correct Chemical Abstracts (CA) name of the substance based on the ninth Collective Index (9CI) of CA nomenclature rules and conventions.

Mark (X) the "Confidential" box next to any item you claim as confidential

Complete either item 1 (Class 1 or 2 substances) or 2 (Polymers) as appropriate. Complete all other items.

If another person will submit chemical identity information for you (for either Item 1 or 2), mark (X) the box at the right. Identify the name, company, and address of that person in a continuation sheet. → ☐

Confi-dential

1. Class 1 or 2 chemical substances (for definitions of class 1 and class 2 substances, see the Instructions Manual)

   a. Class of substance - Mark (X) 1 ☐ Class 1 or 2 ☒ Class 2

   b. Chemical name (Currently correct Chemical Abstracts (CA) Name that is consistent with TSCA Inventory listings for similar substances. For Class 1 substances a CA Index Name must be provided. For Class 2 substances either a CA Index Name or CA Preferred Name must be provided, which ever is appropriate based on CA 9CI nomenclature rules and conventions).

   c. Please identify which method you used to develop or obtain the specified chemical identity information reported in this notice: (check one).

   ☐ Method 1 (CAS Inventory Expert Service - a copy of the Identification report obtained from the CAS Inventory Expert Services must be submitted as an attachment to this notice)

   ☐ Method 2 (Other Source)

   d. Molecular formula and CAS Registry Number (if a number already exists for the substance)

   CAS#

   e. For a class 1 substance, provide a complete and correct chemical structure diagram. For a class 2 substance - (1) List the immediate precursor substances with their respective CAS Registry Numbers. (2) Describe the nature of the reaction or process. (3) Indicate the range of composition and the typical composition (where appropriate). (4) Provide a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained.

☐ Mark (X) this box if you attach a continuation sheet.

Part I -- GENERAL INFORMATION -- Continued

Section B -- CHEMICAL IDENTITY INFORMATION -- Continued

2. Polymers (For a definition of polymer, see the Instructions Manual.)

Confi-dential
X

a. Indicate the number-average weight of the lowest molecular weight composition of the polymer you intend to manufacture. Indicate maximum weight percent of low molecular weight species (not including residual monomers, reactants, or solvents) below 500 and below 1,000 absolute molecular weight of that composition.

Describe the methods of measurement or the basis for your estimates: GPC ☐ Other ☐: (Specify) _____

i) lowest number average molecular weight: _____

ii) maximum weight % below 500 molecular weight: _____

iii) maximum weight % below 1000 molecular weight: _____

☐ Mark (X) this box if you attach a continuation sheet.

b. You must make separate confidentiality claims for monomer or other reactant identity, composition information, and residual information. Mark (X) the "Confidential" box next to any item you claim as confidential

(1) - Provide the specific chemical name and CAS Registry Number (if a number exists) of each monomer or other reactant used in the manufacture of the polymer.
(2) - Mark (X) this column if entry in column (1) is confidential.
(3) - Indicate the typical weight percent of each monomer or other reactant in the polymer.
(4) - Mark (X) the identity column if you want a monomer or other reactant used at two weight percent or less to be listed as part of the polymer description on the TSCA Chemical Substance Inventory.
(5) - Mark (X) this column if entries in columns (3) and (4) are confidential.
(6) - Indicate the maximum weight percent of each monomer or other reactant that may be present as a residual in the polymer as manufactured for commercial purposes.
(7) - Mark (X) this column if entry in column (6) is confidential.

Monomer or other reactant and CAS Registry Number (1)	Confi-dential (2)	Typical composition (3)	Identity Mark (X) (4)	Confi-dential (5)	Maximum residual (6)	Confi-dential (7)
1,2-Ethanediol (107-21-1)		%	X	X	%	X
Epichlorohydrin (106-89-8)		%	X	X	%	X
	X	%		X	%	X
	X	%		X	%	X
	X	%		X	%	X
	X	%		X	%	X
	X	%		X	%	X

☐ Mark (X) this box if you attach a continuation sheet.

c. Please identify which method you used to develop or obtain the specified chemical identity information reported in this notice (check one).

☒ Method 1 (CAS Inventory Expert Service - a copy of the identification report obtained from CAS Inventory Expert Service must be submitted as as attachment to this notice)

☐ Method 2 (other source)

d. The currently correct Chemical Abstracts (CA) name for the polymer that is consistent with TSCA Inventory listings for similar polymers.

1,2-Ethanediol reaction products with epichlorohydrin (CAS 705265-31-2)

e. Provide a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained.

X

☐ Mark (X) this box if you attach a continutation sheet.

Part I -- GENERAL INFORMATION -- Continued

Section B -- CHEMICAL IDENTITY INFORMATION -- Continued

3. Impurities

(a) - Identify each impurity that may be reasonably anticipated to be present in the chemical substance as manufactured for commercial purpose. Provide the CAS Registry Number if available. If there are unidentified impurities, enter "unidentified."

(b) - Estimate the maximum weight % of each impurity. If there are unidentified impurities, estimate their total weight %.

Impurity and CAS Registry Number (a)	Maximum percent (b)	Confi-dential
	%	
	%	
	%	
	%	
	%	
	%	
	%	

☐ Mark (X) this box if you attach a continuation sheet.

4. Synonyms - Enter any chemical synonyms for the new chemical identified in subsection 1 or 2. (Confi-dential)

ethylene glycol diglycidyl ether

☐ Mark (X) this box if you attach a continuation sheet.

5. Trade identification - List trade names for the new chemical substance identified in subsection 1 or 2.

Denacol EX-811/Denacol EX-811R

☐ Mark (X) this box if you attach a continuation sheet.

6. Generic chemical name - If you claim chemical identify as confidential, you must provide a generic name for your substance that reveals the specific chemical identity of the new chemical substance to the maximum extent possible. Refer to the TSCA Chemical Substance Inventory, 1985 Edition, Appendix B for guidance on developing generic names.

☐ Mark (X) this box if you attach a continuation sheet.

7. Byproducts - Describe any byproducts resulting from the manufacture, processing, use, or disposal of the new chemical substance. Provide the CAS Registry Number if available.

Byproduct (1)	CAS Registry Number (2)	Confi-dential

☐ Mark (X) this box if you attach a continuation sheet.

Part I -- GENERAL INFORMATION -- Continued

Section C -- PRODUCTION, IMPORT, AND USE INFORMATION:

Mark (X) the "Confidential" box next to any item you claim as confidential.

1. **Production volume** -- Estimate the **maximum** production volume during the first 12 months of production. Also estimate the maximum production volume for any consecutive 12-month period during the first three years of production. Estimates should be on 100% new chemical substance basis. For a Low Volume Exemption application, if you choose to have your notice reviewed at a lower production volume than 10,000 kg/yr, specify the volume and mark (x) in the binding box. If granted, you are bound to this volume

Maximum first 12-month production (kg/yr) (100% new chemical substance basis)	Maximum 12-month production (kg/yr) (100% new chemical substance basis)	Confi-dential	Binding Option Mark (x)
		X	

2. **Use Information** -- You must make separate confidentiality claims for the description of the category of use, the percent of production volume devoted to each category, the formulation of the new substance, and other use information. Mark (X) the "Confidential" Box next to any item you claim as confidential.

a. (1) -- Describe each intended category of use of the new chemical substance by function and application..
(2) -- Mark (X) this column if entry column (1) is confidential business information (CBI).
(3) -- Indicate your willingness to have the information provided in column (1) binding.
(4) -- Estimate the percent of total production for the first three years devoted to each category of use.
(5) -- Mark (X) this column if entry in column (4) is confidential business information (CBI).
(6) -- Estimate the percent of the new substance as formulated in mixtures, suspensions, emulsions, solutions, or gels as manufactured for commercial purposes at sites under your control associated with each category of use.
(7) -- Mark (X) this column if entry in column (6) is confidential business information (CBI).
(8) -- Indicate % of product volume expected for the listed "use" sectors. Mark more than one box if appropriate. Mark (X) to indicate your willingness to have the use type provided in (8) binding.
(9) -- Mark (X) this column if entry(ies) in column (8) is (are) confidential business information (CBI).

Category of use (1) (by function and application i.e. a dispersive dye for finishing polyester fibers)	CBI (2)	Binding Option Mark (x) (3)	Production % (4)	CBI (5)	% in Formulation (6)	CBI (7)	% of substance expected per use (8) Site-limited	Consumer*	Industrial	Commercial	Binding Option	CBI (9)
	X	X	%	X	%	X					X	X
			%		%							
			%		%							
			%		%							
			%		%							
			%		%							
			%		%							

* If you have identified a "consumer" use, please provide on a continuation sheet a detailed description of the use(s) of this chemical substance in consumer products. In addition include estimates of the concentration of the new chemical substance as expected in consumer products and describe the chemical reactions by which this substance loses its identity in the consumer product.

☐ Mark (X) this box if you attach a continuation sheet.

b. Generic use description -- If you claim any category of use description in subsection 2a as confidential, enter a generic description of that category. Read the Instructions Manual for examples of generic use descriptions.

industrial reactant

☐ Mark (X) this box if you attach a continuation sheet.

3. **Hazard Information** -- Include in the notice a copy of reasonable facsimile of any hazard warning statement, label, material safety data sheet, or other information which will be provided to any person who is reasonably likely to be exposed to this substance regarding protective equipment or practices for the safe handing, transport, use, or disposal of the new substance. List in part III hazard information you include.

Binding Option Mark (x)

☒ Mark (X) this box if you attach hazard information.

Part II-- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

Section A -- INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER

Mark (X) the "Confidential" box next to any item you claim as confidential

Complete section A for each type of manufacture, processing, or use operation involving the new chemical substance at industrial sites you control. Importers do not have to complete this section for operations outside the U.S.; however, you may still have reporting requirements if there are further industrial processing or use operations after import. You must describe these operations. See instructions manual

1. Operation description	Confi-dential
a. Identity -- Enter the identity of the site at which the operation will occur.	
Name	
Site address (number and street)	
City, County, State, ZIP code	
If the same operation will occur at more than one site, enter the number of sites. Identify the additional sites on a continuation sheet, and if any of the sites have significantly different production rates or operations, include all the information requested in this section for those sites as attachments. →	
☐ Mark (X) this box if you attach a continuation sheet.	
b. Type -- Mark (X) ☐ Manufacturing ☐ Processing ☐ Use	
c. Amount and Duration -- Complete 1 or 2 as appropriate	

	Maximum kg/batch (100% new chemical substance)	Hours/batch	Batches/year
1. Batch			
2. Continuous	Maximum kg/batch (100% new chemical substance)	Hours/batch	Batches/year

d. Process description ☐ Mark (X) to indicate your willingness to have your process description binding.

(1) Diagram the major unit operation steps and chemical conversions. Include interim storage and transport containers (specify- e.g. 5 gallon pails, 55 gallon drum, rail car, tank truck, etc.).

(2) Provide the identity , the approximate weight (by kg/day or kg/batch on a 100% new chemical substance basis), and entry point of all starting materials and feedstocks (including reactants, solvents, catalysts, etc.), and of all products, recycle streams, and wastes. Include cleaning chemicals (note frequency if not used daily or per batch.).

(3) Identify by number the points of release, including small or intermittent releases, to the environment of the new chemical substance.

☐ Mark (X) this box if you attach a continuation sheet.

Part II-- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE -- Continued

Section A -- INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER -- Continued

2. **Occupational Exposure** -- You must make separate confidentiality claims for the description of worker activity, physical form of the new chemical substance, number of works exposed, and duration of activity. Mark (X) the "Confidential" box next to any item you claim as confidential.
   (1) -- Describe the activities (i.e. bag dumping, tote filling, unloading drums, sampling, cleaning, etc.) in which workers may be exposed to the substance.
   (2) -- Mark (X) this column if entry in column (1) is confidential business information (CBI).
   (3) -- Describe any protective equipment and engineering controls used to protect workers.
   (4) and (6) -- Indicate your willingness to have the information provided in column (3) or (5) binding.
   (5) -- Indicate the physical form(s) of the new chemical substance (e.g., solid: crystal, granule, powder, or dust) and % new chemical substance (if part of a mixture) at the time of exposure.
   (7) -- Mark (X) this column if entry in column (5) is confidential business information (CBI).
   (8) -- Estimate the maximum number of workers involved in each activity for all sites combined.
   (9) -- Mark (X) this column if entry in column (8) is confidential business information (CBI).
   (10) and (11) -- Estimate the maximum duration of the activity for any worker in hours per day and days per year.
   (12) -- Mark (X) this column if entries in columns (10) and (11) are confidential business information (CBI).

Worker activity (i.e., bag dumping, filling drums) (1)	CBI (2)	Protective Equipment/ Engineering Controls (3)	Binding Option Mark (x) (4)	Physical forms(s) and % new substance (5)	Binding Option Mark (x) (6)	CBI (7)	# of Workers Exposed (8)	CBI (9)	Maximum Hrs/day (10)	duration Days/yr (11)	CBI (12)

☐ Mark (X) this box if you attach a continuation sheet.

3. **Environmental Release and Disposal** -- You must make separate confidentiality claims for the release number and the amount of the new chemical substance released and other release and disposal information. Mark (X) the "Confidential" box next to each item you claim as confidential.
   (1) -- Enter the number of each release point identified in the process description, part II, section A, subsection 1d(3).
   (2) -- Estimate the amount of the new substance released (a) directly to the environment or (b) into control technology (in kg/day or kg/batch).
   (3) -- Mark (X) this column if entries in columns (1) and (2) are confidential business information (CBI).
   (4) -- Identify the media (stack air, fugitive air (optional-see Instruction Manual), surface water, on-site or off-site land or incineration, POTW, or other (specify)) to which the new substance will be released from that release point.
   (5) -- a. Describe control technology, if any, and control efficiency that will be used to limit the release of the new substance to the environment. For releases disposed of on land, characterize the disposal method and state whether it is approved for disposal of RCRA hazardous waste. On a continuation sheet, for each site describe any additional disposal methods that will be used and whether the waste is subject to secondary or tertiary on-site treatment. b. Estimate the amount released to the environment after control technology (in kg/day).
   (6) -- Mark (X) this column if entries in columns (4) and (5) are confidential business information (CBI).
   (7) -- Identify the destination(s) of releases to water. Please supply NPDES (National Pollutant Discharge Elimination System) numbers for direct discharges or NPDES numbers of the POTW (Publicly Owned Treatment Works). Mark (X) if the POTW name or NPDES # is confidential business information (CBI).

Release Number (1)	Amount of new substance released (2a)	(2b)	CBI (3)	Media of release e.g. stack air (4)	Control technology and efficiency (you may wish to optionally attach efficiency data) (5a)	Binding Mark (X)	(5b)	CBI (6)

(7) Mark (X) the destination(s) of releases to water.	☐ POTW provide name(s) below: _____	CBI	☐ Navigable waterway	☐ Other - Specify	provide NPDES #	CBI

☐ Mark (X) this box if you attach a continuation sheet.

Part II-- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE -- Continued

Section B -- INDUSTRIAL SITES CONTROLLED BY OTHERS

Complete section B for typical processing or use operations involving the new chemical substance at sites you do not control. Importers do not have to complete this section for operations outside the U.S.; however, you must report any processing or use activities after import. See the Instructions Manual. *Complete a separate section B for each type of processing, or use operation involving the new chemical substance.* If the same operation is performed at more than one site describe the typical operation common to these sites. Identify additional sites on a continuation sheet.

1. **Operation Description** -- To claim information in this section as confidential, circle or bracket the specific information that you claim as confidential. (1) -- Diagram the major unit operation steps and chemical conversions, including interim storage and transport containers (specify - e.g. 5 gallon pails, 55 gallon drums, rail cars, tank trucks, etc). On the diagram, identify by letter and briefly describe each worker activity. (2) -- Provide the identity, the approximate weight (by kg/day or kg/batch, on an 100% new chemical substance basis), and entry point of all feedstocks (including reactants, solvents and catalysts, etc) and all products, recycle streams, and wastes. Include cleaning chemicals (note frequency if not used daily or per batch). (3) -- Identify by number the points of release, including small or intermittent releases, to the environment of the new chemical substance. (4) Please enter the # of sites (remember to identify the locations of these sites on a continuation sheet):

_____
# of sites

☐ Mark (X) this box if you attach a continuation sheet.

2. **Worker Exposure/Environmental Release**
   (1) -- From the diagram above, provide the letter for each worker activity. Complete 2-8 for each worker activity described.
   (2) -- Estimate the number of workers exposed for all sites combined.
   (4) -- Estimate the typical duration of exposure per worker in (a) hours per day and (b) days per year.
   (6) -- Describe physical form of exposure and % new chemical substance (if in mixture), and any protective equipment and engineering controls, if any, used to protect workers.
   (7) -- Estimate the percent of the new substance as formulated when packaged or used as a final product.
   (9) -- From the process diagram above, enter the number of each release point. Complete 9-13 for each release point identified.
   (10) -- Estimate the amount of the new substance released (a) directly to the environment or (b) into control technology to the environment (in kg/day or kg/batch).
   (12) -- Describe media of release i.e. stack air, fugitive air (optional-see Instructions Manual), surface water, on-site or off-site land or incineration, POTW, or other (specify) and control technology, if any, that will be used to limit the release of the new substance to the environment.
   (14) -- Identify byproducts which may result from the operation.
   (3), (5), (8), (11), (13) and (15) -- Mark (X) this column if any of the proceeding entries are confidential business information (CBI).

Letter of Activity (1)	# of Workers Exposed (2)	CBI (3)	Duration of Exposure (4a)	(4b)	CBI (5)	Protective Equip. / Engineering Controls/ Physical Form and % new substance (6)	% in Formulation (7)	CBI (8)	Release Number (9)	Amount of New Substance Released (10a)	(10b)	CBI (11)	Media of Release & Control Technology (12)	CBI (13)
		X			X			X				X		X

(14) -- Byproducts:
None anticipated

(15)

☐ Mark (X) this box if you attach a continuation sheet.

OPTIONAL POLLUTION PREVENTION INFORMATION

To claim information in this section as confidential circle or bracket the specific information that you claim as confidential.

In this section you may provide information not reported elsewhere in this form regarding your efforts to reduce or minimize potential risks associated with activities surrounding manufacturing, processing, use and disposal of the PMN substance. Please include new information pertinent to pollution prevention, including source reduction, recycling activities and safer processes or products available due to the new chemical substance. Source reduction includes the reduction in the amount or toxicity of chemical wastes by technological modification, process and procedure modification, product reformulation, raw materials substitution, and/or inventory control. Recycling refers to the reclamation of useful chemical components from wastes that would otherwise be treated or released as air emissions or water discharges, or land disposal. Descriptions of pollution prevention, source reduction and recycling should emphasize potential risk reduction subsequent to compliance with existing regulatory requirements and can be either quantitative or qualitative. The EPA is interested in the information to assess overall net reductions in toxicity or environmental releases and exposures, not the shifting of risks to other environmental media or non-environmental areas (e.g., occupational or consumer exposure). In addition, information on the relative cost or performance characteristics of the PMN substance to potential alternatives may be provided.

All information provided in this section will be taken into consideration during the review of this substance. See Instructions Manual and Pollution Prevention Guidance manual for guidance and examples.

Describe the expected net benefits, such as (1) an overall reduction in risk to human health or the environment; (2) a reduction in the volume manufactured; (3) a reduction in the generation of waste materials through recycling, source reduction or other means; (4) a reduction in potential toxicity or human exposure and/or environmental release; (5) an increase in product performance, a decrease in the cost of production and/or improved operation efficiency of the new chemical substance in comparison to existing chemical substances used in similar application; or (6) the extent to which the new chemical substance may be a substitute for an existing substance that poses a greater overall risk to human health or the environment.

☐ Mark (X) this box if you attach a continuation sheet.

Part III -- LIST OF ATTACHMENTS

Attach continuation sheets for sections of the form and test data and other data (including physical/chemical properties and structure/activity information), and optional information after this page. Clearly identify the attachment and the section of the form to which it relates, if appropriate. Number consecutively the pages of the attachments. In the column below, enter the inclusive page numbers of each attachment.

Mark (X) the "Confidential" box next to any attachment name you claim as confidential. Read the Instructions Manual for guidance on how to claim any information in an attachment as confidential. You must include with the sanitized copy of the notice form a sanitized version of any attachment in which you claim information as confidential.

Attachment name	Attachment page number(s)	Confi-dential
Material Safety Data Sheet (MSDS)	14-17	
Physical and Chemical Property Worksheet	13	
CAS Inventory Expert Service Report	18	
MITES Report - Mutagenicity Test	19-27	
GPC data for Denacol EX-811 and EX-811R	28-31	X

☐ Mark (X) this box if you attach a continuation sheet. Enter the attachment name and number.

PHYSICAL AND CHEMICAL PROPERTIES WORKSHEET

To assist EPA's review of physical and chemical properties data, please complete the following worksheet for data you provide and include it in the notice. Identify the property measured, the page of the notice on which the property appears, the value of the property, the units in which the property is measured (as necessary), and whether or not the property is claimed as confidential. The physical state of the neat substance should be provided. These measured properties should be for the neat (100% pure) chemical substance. Properties that are measured for mixtures or formulations should be so noted (% PMN substance in __). You are not required to submit this worksheet; however, EPA strongly recommends that you do so, as it will simplify review and ensure that confidential information is properly protected. You should submit this worksheet as a supplement to your submission of test data. This worksheet is not a substitute for submission of test data.

Property (a)	Mark (X) if provided	Page number (b)	Value (c)	Measured or Estimate (M or E)	Confidential Mark (X) (d)
Physical state of neat substance			____(s) __X(l) ___(g)	E	
Vapor pressure @ Temperature __°C					
Density/relative density			1.17 (25 deg C/4 deg C)	M	
Solubility @ Temperature _____°C Solvent _____					
Solubility in water @ Temperature _____°C			Soluble	E	
Melting temperature					
Boiling / sublimation temperature@___					
Spectra, infrared					
Dissociation constant					
Particle size distribution					
Octanol / water partition coefficient					
Henry's Law constant					
Volatilization from water					
Volatilization from soil					
pH@ concentration _____					
Flammability-Flash Point			148 deg C (open cup)	M	
Explodability					
Adsorption / coefficient					
Other –Appearance			Clear liquid	E	
Other –Odor			odorless	E	

MATERIAL SAFETY DATA SHEET

Prepared Date : 4/21/2008

Revised Date : 1/23/2008

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1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name : DENACOL EX-811R

PRODUCT Identification :

Manufacturer/Supplier : Nagase ChemteX Corporation,236 Nakai Tatsuno-cho Tatsuno City Hyogo JAPAN

MSDS Prepared by : Functional Chemicals Division, Nagase ChemteX Corporation

For Emergency Health : 0791-63-9093 (JAPAN)

For Other Information : 0791-63-9087 (JAPAN)

Chemical Name : Ethyleneglycol Diglycidyl Ether

Molecular Formula : C8H14O4 (model compound)

Product Use : Polymer additive

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2. COMPOSITION / INFORMATION ON INGREDIENTS

Weight %	Component	(CAS Registry No)
99 min.	Ethyleneglycol Diglycidyl Ether	(705265-31-2)

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3. HAZARDS IDENTIFICATION (HMIS Hazard Rating)

Health : 2

Flammability : 1 Chemical Reactivity : 1

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4. FIRST-AID MEASURES

Inhalation : If symptomatic, move to fresh air. Get medical attention if symptoms persist.

Eyes : Immediately flush with plenty of water at least 15 minutes. Get medical attention.

Skin : Immediately flush with plenty of water.

Ingestion : Induce vomiting and seek medical help.

5. FIRE FIGHTING MEASURES

Extinguish media : Carbon dioxide, dry chemicals and their equivalents

Special Fire-Fighting Procedure : Firefighters should wear proper protective equipment and self-contained breathing apparatus with full face piece and protective clothing.

Hazardous Combustion Products : Carbon dioxide, carbon monoxide

Unusual Fire and Explosion Hazards : None

6. ACCIDENTAL RELEASE MEASURES

Immediately soak up with absorbents and discard correctly. Clean the spillage site with detergent and water then flush to foul water drain with a large volume of water.

7. HANDLING AND STORAGE

Personal Precautionary Measures : Care should be taken to prevent direct touch. In case of contact flush skin immediately with plenty of water and remove contaminated clothing.

Prevention of Fire and Explosion : Keep away from strong acids, bases, and certain metallic salts.

Storage : Keep container well closed. Store below 35℃ for not more than 180 days. Keep away from heat, sparks, and flame.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limits :

AGGIH Threshold Limit Value (TLV) : Not established

OSHA (USA) Permissible Exposure Limit : Not established

Respiratory protection : Use charcoal gas mask in case of exposure to vapor.

Ventilation : Sufficient to minimize vapor if generated.

Eye Protection : Use chemical goggles

Skin protection : Use impervious gloves. Body-covering clothing should be needed.

Other protective equipment : Eye fountain and safety shower near work area.

9.PHYSICAL AND CHEMICAL PROPERTIES

Physical form : Clear liquid

Color : Pale yellow

Odor : None

Specific gravity : 1.17 (25℃/4℃)

Boiling point : No data

Solubility in water : Soluble

Flash point : 148℃ (open cup)

10. STABILITY AND REACTIVITY

Stability : Regular storage conditions are applied. Store below 35℃ for not more than 180 days.

Incompatibility : Material can react with strong acids and bases, and oxidizing agents, epoxy hardeners.

Hazardous polymerization : Might occur in high temperature and in the presence of certain catalysts.

Hazardous decomposition products : None

11. TOXICOLOGICAL INFORMATION

SKIN : Primary Irritation Index 5.3 (rabbit) Moderate to severe

INGESTION : No data

MUTAGENICITY : Ames test ; Positive (*Salmonella Typhimurium*, TA- 100)

INHALATION : No data

12. ECOLOGICAL INFORMATION

BIODEGRADATION : No data

13. DISPOSAL CONSIDERATION

Discharge, treatment, or disposal may be subjected to national, state, or local laws.

Incinerate.

Since emptied containers retain product residue, follow label warnings even after container is emptied.

14. TRANSPORT INFORMATION

UN Class : Not classified

IMO Class : Not classified

15. REGULATELY INFORMATION

US Toxic Substances Control Act (TSCA) :

Alternate CAS# 2224-15-9

European Inventory of Existing Commercial Chemical Substances (EINECS) :

EINECS Number : 218-746-2

Japanese Handbook of Existing and New Chemical Substances:

Registered Number : 2-396

16. OTHER INFORMATION

Label Statements :

WARNING : Harmful

Harmful by inhalation, in contact with skin, if swallowed.

Irritating to eyes. Irritating to skin. Avoid contact with eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

After contact with skin, wash immediately with plenty of water. Wear suitable gloves.

Wear eye/face protection. Wash thoroughly after handling.

FIRST AID : In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention. Do not peel from skin.

CAUTION : FOR MANUFACTURING, PROCESSING OR REPACKING BY TRAINED PERSONNEL

The information contained herein is based on current knowledge and experience ; No responsibility is accepted that the information is sufficient or correct in all cases. Users should consider these data only as a supplement to other information gathered by them and must make independent determination of suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers and the protection of the environment.

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INVENTORY EXPERT SERVICE REPORT

IES-ORDER NUMBER: 120108-2

REGISTRY NUMBER: 705265-31-2

CA INDEX NAME

1,2-Ethanediol, reaction products with epichlorohydrin

Please print the above CA Index Name on the appropriate page of your PMN.

☐ **If this box is checked, CAS has made correction(s) marked in red to your IES order. Please make the same correction(s) to your PMN before submitting it to the EPA.**

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Nagase & Co., Ltd.

MITES REPORT No. 53-158

Study Report

Mutagenicity test

September 8, 1978

Mitsubishi Kasei Anzen Kagaku Kenkyusho

1. Abstract

Mutagenicity of 6 epoxy compounds was examined in *Salmonella typhymurim* TA100 *in vitro* with or without metabolic activation. As a result, every test sample was found to have mutagenicity according to a sensitive method using pre-incubation.

2. Test samples

Test samples: Viscous fluid samples carrying the following indications that were supplied by Nagase &. Co., Ltd. and received on July 20, 1978.

(1)	Denacol	EX-313	(Lot QF 561)	(I)
	Denacol	EX-314	(Lot QF 446)	(II)
	Denacol	EX-310	(R 780717)	(III)
	Denacol	EX-851	(R 771220)	(IV)
	Denacol	EX-811	(Lot QE 102)	(V)
	EPON-812			(VI)

As a solvent, dimethyl sulfoxide was used.

3. Test method

(1) Used bacterial strain

Salmonella typhimurium TA 100[(1)]

(2) Culture media

Culture media:

(2-1) Nutrient broth medium

Nutrient broth	8 g
NaCl	5 g
Dist. Water	1000 ml

Adjust the pH to 7.0 with 50% KOH.

(2-2) Medium for Salmonella

$MgSO_4 \cdot 7H_2O$	0.2 g
Citric acid	2 g
$K_2 HPO_4$	10 g
$NaNH_4 HPO_4 \cdot 4H_2O$	3.5 g
Glucose	20 g
Histidine	0.620 mg
Biotin	0.976 mg
Agar	15 g
Dist. Water	1000 ml

(3) S-9 Mixture

To male rats (body weight: about 200 g), 500 mg/kg PCB (Aroclor/254) dissolved in corn oil is administered by intraperitoneal injection. After rearing for 1 week, each animal is killed by exsanguination, and the liver is extracted. The liver is homogenized with a homogenizer, and centrifuged at 9000 G. The supernatant is called S-9 [2]. This fraction contains microsomes, and also, 30 – 40 mg/ml protein.

Liver microsome Supernatant (S-9)	0.3 ml/ml
$MgCl_2$	8 mM
KCl	33 mM
Glucose-6-phosphate	5 mM
NADPH	4 mM
NADH	4 mM
$Na_2 HPO_4 – KH_2 PO_4$ buffer (pH 7.4)	100 mM

(4) Experimental methods

Reverse mutation method

S. typhimurium is cultured in the nutrient broth liquid medium for 24 hours by shaking. To 0.1 ml of this preculture fluid, 0.5 ml of S-9 mix and 0.05 ml of a sample are added and mixed, and the mixture is subjected to pre-incubation at 37°C for 20 minutes by shaking [3]. This process is for metabolically activating the sample *in vitro*, and letting the activated sample act on the bacterium in the liquid phase. For the sample without metabolic activation, S-9 of the S-9 mix is replaced by 0.15 M KCl. Thereafter, the mixture is quickly mixed with 2 ml of soft agar (0.6% NaCl and 0.6% agar at 45°C), poured on a culture plate for Salmonella and spread evenly by moving the plate.

The plate is incubated at 37°C for about 45 hours in an incubator.

After incubation, the number of developed colonies is counted. When the number is larger than that with the negative control (only the solvent, dimethyl sulfoxide) by several times, and the increase in the colony number is proportional to the amount of added test sample, the mutagenicity of the test sample is judged to be positive.

4. Test Results

Strain	Compound	Amount[a] μg/plate	Revertant	colonies/ plate[b]	Mutagenicity
TA 100	EX-313	1000	739 -	589 -	+
		500	391 -	427 -	
		200	274 -	308 -	
		0 [c]	146 -	137 -	
	EX-314	1000	766 -	528 -	+
		500	326 -	373 -	
		200	202 -	243 -	
		0	146 -	137 -	
	EX-310	1000	359 -	471 -	+
		500	264 -	346 -	
		200	202 -	126 -	
		0	146 -	137 -	
	EX-851	1000	694 -	600 -	+
		500	308 -	397 -	
		200	227 -	239 -	
		0	146 -	137 -	
	EX-811	1000	689 -	795 -	+
		500	400 -	359 -	
		200	255 -	311 -	
		0	146 -	137 -	
	Epon 812	2000	1440 -	528 -	+
		1000	598 -	311 -	
		500	421 -	186 -	
		0	146 -	137 -	
	Benzo (a) pyrene	50	1566 -		

a: The maximum dose was set at 100 μg/plate, and lower doses were set in a geometric series with an appropriate factor.

+ or − put on the right side of each colony number indicates bactericidal effect.

b: Number of his^+ revertant colonies

c: Solvent; dimethyl sulfoxide, 0.05 ml

Supplement: 1

In the case of detection of mutagenicity with microorganisms, the range of mutagenicity is more than 10^4. Therefore, if a trace of strongly mutagenic substance is mixed, the main component of the sample can be judged to be apparently mutagenic on occasion.

In the case of the samples in this study, epichlorohydrin can be a possible impurity as shown above, and its mutagenicity was measured under the same conditions.

The results are shown below. Judging from its content, it is unthinkable that the mutagenicity of the test samples is attributed to residual epichlorohydrin.

Mutagenicity of epichlorohydrin in TA100

Strain	Compound	Amount[a] μg/plate	Revertant colonies/ plate[b]		Mutagenicity
TA 100		500	501 -	911 -	
		100	167 -	184 -	
		20	140 -	167 -	+
		5	154 -	155 -	
		0 *1	122 -	186 -	

*1: Solvent dimethyl sulfoxide, 0.05 ml

References

1. Ames, B. N., F. D. Lee and W. E. Durston, An improved bacterial test system for the detection and classification of mutagens and carcinogens, Proc. Natl. Acad. Sci. (U. S.) 70 (1973) 782-786.

2. McCann, J., N. E. Spingarn, J. Kobori and B. N. Ames, Detection of carcinogens as mutagens: bacterial tester strains with R factor plasmids, Proc. Natl. Acad. Sci. (U. S.), 72 (1975) 979-983.

3. Hill, R. F., Ultraviolet-induced lethality and reversion to prototrophy in Escherichia coli strains with normal and reduced dark repair ability, Photochem. photobio., 4 (1965) 563-568.

4. Witkin, E. M., Time, temperature, and protein synthesis: a study of ultraviolet-induced mutation in bacteria, Cold Spring Harbor Quant. Biol., 21 (1956) 123-140.

5. Ames, B. N., W. E. Durston, E. Yamasaki and F. D. Lee, Carcinogens are mutagens: a simple test system combining liver homogenates for activation and bacteria for detection, Proc. Natl. Acad. Sci. (U. S.), 70 (1973) 2281-2285.

6. Yahagi, T., Degawa, M., Seino, Y., Matsushima, T., Nagao, M., Sugimura, T., and Hashimoto, Y. Mutagenicity of carcinogenic azo dyes and their derivatives. Cancer Letters, 1 (1975) 91-96